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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/455,978

Applicant(s)

ALAM ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-16, 48, 49, 51-54, 64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-50, 52 and 54 is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-15, 53 and 64-67 is/are rejected.
- 7) ☒ Claim(s) 6 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The Amendment filed August 7, 2003 has been entered and considered. Claims 7-10, 17-47, 50, and 55-63 have been cancelled. Claims 66 and 67 have been added. Therefore, Claims 1-6, 11-16, 48-49, 51-54, 64, and 65 are pending and have been considered on the merits in this Office Action.

Drawings

The drawings filed August 7, 2003 are accepted by the Examiner.

Rejections Withdrawn

The rejection of Claims 1-5, 11-15, and 64-65 under 35 U.S.C. 102(b) as being anticipated by Gong et al. (Proc. Natl. Acad. Sci. (Dec. 1998) 95: 15177-15182) is withdrawn in light of the amendments.

The rejection of Claims 5, 15, and 53 under 35 U.S.C. 112, second paragraph as indefinite as to the metes and bounds of "salt tolerant" is withdrawn in light of Applicant's arguments.

The rejection of Claim 65 under 35 U.S.C. 112, second paragraph for lack of antecedent basis is withdrawn in light of the amendment.

The rejection of Claims 1-5, 64, and 65 under 35 U.S.C. 112, second paragraph as indefinite because its unclear what myoglobin sequence is the reference sequence

to which the claimed heme binding protein is compared is withdrawn in light of the amendment.

The rejection of Claims 1-5, 11-15, 64 and 65 under 35 U.S.C. 112, second paragraph as indefinite as to the metes and bounds of "low affinity" is withdrawn in light of Applicants arguments.

Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is rejected because the scope of the claim is unclear. Claim 64 appears to broaden Claim 1 since the fragment claimed therein must only contain a heme-binding domain and since it does not appear that Claim 64 requires that the heme-binding domain comprises SEQ ID NO:76 as required in Claim 1. Clarification is required. An amendment such as "... wherein the fragment comprises the myoglobin heme binding domain having the sequence of SEQ ID NO:76" would be appropriate to overcome this rejection.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 11-15, 53 and 64-67 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Specification does not provide a structure-function relationship

The present claims are drawn to proteins that have a specified activity and minimal structure (a heme binding domain that has at least 20% identity to the sequence of SEQ ID NO:76). Claims 5, 15, and 53 further limit the protein to those that are "salt tolerant". However, the Specification does not provide any information about what modifications to the sequence of SEQ ID NO:76 can be made without eliminating the specified activities. What characteristics of SEQ ID NO:76 allow a protein to reversibly bind oxygen with low affinity or to be "salt-tolerant"? The Specification is silent with regard to this information. Thus, with the Specification in hand, one of skill in the art would not be able to recognize which of all of the sequences that are 20% identical to SEQ ID NO:76 would have the claimed activities. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure in function. However, without such correlation, the capability to recognize or understand the structure from mere recitation of function and

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minimal structure is highly unlikely and does not satisfy the written description requirements.

The Specification does not set forth the invention in terms of distinguishing identifying characteristics that would allow one of skill in the art to recognize a sequence as being "bacterial" or from Archaea" or from "H. salinarum".

Applicants' response (August 7, 2003) to the prior art rejections states that "bacterial" is a property of the claimed protein. However, the Specification nor the response identifies what property of the protein characterizes it as being "bacterial" or from "Archaea", or from "H. salinarum". At the time of the invention, recombinant technology was routine and proteins were routinely modified and recombinantly produced from sources different from the source of the originating protein. Thus, if a protein isolated from bacteria were changed by one amino acid, would it still be considered "bacterial"? If so, when does the protein cease to be considered "bacterial"—how much modification is allowed to maintain its identity as "bacterial"? These questions are not answered in the present Specification or the art. Thus, one of skill in the art would not know what sequences of all of the sequences that have 20% identity to SEQ ID NO:76 would be considered "bacterial" sequences or sequences from "Archaea" or from "H. salinarum". Thus, the claims do not meet the written description requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Proc. Natl. Acad. Sci (1996) Vol. 93, pp. 4649-4654 ; ref. 16 in IDS of Paper No. 4).

Response to Applicants arguments:

Applicants argue (1) that the full protein sequence did not become available until after the filing date of the present application, (2) that Zhang et al. only reports partial amino acid sequence of the HtB protein, and (3) that Zhang et al. does not teach isolation of the protein. These arguments have been considered but are not deemed persuasive for the following reasons:

(1) The present claims are drawn to a product. Thus, the issue at hand is whether or not the product was described prior to the filing of the present application and not whether the inherent properties of the product were known. Zhang et al. describes a protein (HtB) that meets the limitations of the claims. Zhang et al. also provides sufficient information (amino acid sequence, method of isolation (fig. 5)) such that one of skill in the art could isolate the HtB protein upon reading Zhang et al.

(2) While Zhang et al. only reports a partial sequence, Zhang et al. discloses that the full sequence of HtB had been obtained (see p. 4652, Col. 2, 4th line from bottom and Table 1). In addition, as stated above, Zhang et al. disclose the HtB protein which

is identical to the proteins presently claimed. It is irrelevant that Zhang et al. only published a partial sequence for the disclosed protein because Zhang et al. disclosed the protein and its isolation. Thus, Zhang et al. is evidence that the claimed protein was known in the prior art.

(3) The examiner disagrees with Applicants contention that Zhang et al. doesn't teach the isolation of the protein. As stated in the previous Office Action, Zhang et al. teaches the fractionation of soluble in membrane bound proteins (see Col. 1, lines 5-23). The claims are not limited to any degree of purity. And, while the Zhang et al. isolation of HtB may be crude, the HtB protein of Zhang et al. is isolated from cells and thus is considered an isolated protein.

Rejection:

Zhang et al. teach a heme binding protein, HtB, which has 100% identity to the sequence of SEQ ID NO:2 (see sequence alignment attached to this Office Action). Zhang et al. teach that the proteins disclosed therein are from *Halobacterium salinarum*, a member of *Archaea* (p. 4649, Col. 1, last paragraph). The properties of a protein are a function of its sequence. Therefore, it is inherent that the HtB protein disclosed in Zhang et al. has all of the properties of Claims 1-6 (such as reversibly binding oxygen with low affinity, having 20% identity to a myoglobin heme binding domain, salt tolerance, etc.) since these are the properties of the protein of SEQ ID NO: 2. Figure 5 (p. 4653) shows the SDS/PAGE analysis of the proteins from *H. salinarum* after fractionation of soluble and membrane-bound proteins (see Col. 1, lines 15-23). Thus,

the protein disclosed in Zhang et al. is considered to be isolated by the fractionation and gel analysis.

Claims 1, 3-5, 11, 13-15, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Grinstaff et al. (U.S. Patent No. 5,635,207).

Response to Arguments:

Applicants argue that the source of the protein as "bacterial" is not a process limitation but a property of the claimed protein. Because the protein does not exist in isolated form in nature, designation of its source organism defines a property that can distinguish one heme binding protein from another (bacterial from mammalian). This argument has been considered but is not deemed persuasive. The present issue is whether or not the claimed product can be distinguished over the prior art. The claims are drawn to a product. If the prior art teaches a product that is identical to the claimed product, the claimed product is not patentable, even if it comes from another source, unless that source imparts some property that distinguishes the claimed product from the prior art. In the present case, there is not a description in the present Specification or the prior art of what features of the sequence identify heme binding proteins as being "bacterial" or from Archaea or from *H. salinarum*. Thus, without such a description or any evidence that the proteins of Grinstaff et al. are distinguishable from the claimed proteins, Grinstaff et al. appears to meet the limitations of the claims.

Rejection:

Grinstaff et al. teach and claim a method of preparing a blood substitute comprising myoglobin (see Claim 3). Myoglobin is considered a heme binding protein that reversibly binds oxygen with a low affinity and would have 100% identity to a myoglobin heme binding domain. The limitation in the present claims that the heme binding proteins are bacterial or that they are isolated from Archaea or *H. salinarum* has been treated similarly to a product-by-process (for example, protein made by the process of isolation from bacteria). “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production” (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 MPEP 2113 and MPEP 2113)). In the instant case, the Specification does not provide a description of what features of the sequence identify a heme binding protein as being “bacterial” or from Archaea or from *H. salinarum*. Thus, without such a description, the protein and blood substitute described in Grinstaff et al. appears to be patentably indistinguishable from that of the instant claims. It is an inherent property of myoglobin that its activity is “tolerant” to at least a small amount of salt (see rejections below for evidence of myoglobin’s salt tolerance).

Claims 1, 3-5, 11, 13-15, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugimoto et al. (Biophysical Journal (Nov. 1998) 75: 2188-2194).

Response to Arguments:

Applicants argue that the source of the protein as "bacterial" is not a process limitation but a property of the claimed protein. Because the protein does not exist in isolated form in nature, designation of its source organism defines a property that can distinguish one heme binding protein from another (bacterial from mammalian). Applicants state that the genetic origin of the Sugimoto et al. protein is not the recombinant host (bacterial)) but mammalian. This argument has been considered but is not deemed persuasive. The present issue is whether or not the claimed product can be distinguished over the prior art. The claims are drawn to a product. If the prior art teaches a product that is identical to the claimed product, the claimed product is not patentable, even if it comes from another source, unless that source imparts some property that distinguishes the claimed product from the prior art. In the present case, there is not a description in the present Specification or the prior art of what features of the sequence identify heme binding proteins as being "bacterial" or from Archaea or from *H. salinarum*. Thus, without such a description or without any evidence that the proteins of Sugimoto et al. are distinguishable over the claimed proteins, the claimed proteins do not appear to be patentable over Sugimoto et al.

Rejection:

Sugimoto et al. disclose the expression, isolation, and purification of recombinant myoglobin from *E. coli*. Myoglobin is considered a heme binding protein that reversibly binds oxygen with low affinity and would have 100% identity to a myoglobin heme binding domain. The limitation in the present claims that the heme binding proteins are bacterial or that they are isolated from Archaea or *H. salinarum* has been treated

similarly to a product-by-process (for example, protein made by the process of isolation from bacteria). “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production” (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 MPEP 2113 and MPEP 2113)). In the instant case, the Specification does not provide a description of what features of the sequence identify a heme binding protein as being “bacterial” or from Archaea or from *H. salinarum*. Thus, without such a description, the protein and blood substitute described in Grinstaff et al. appears to be patentably indistinguishable from that of the instant claims. The protein is contained in a 0.1 M potassium phosphate buffer and therefore appears to be “salt tolerant”. Since the blood substitute compositions are not limited to having any components other than the heme binding protein, the composition of the purified myoglobin in buffer appears to meet the limitations of Claims 11-15. Thus, the reference meets the limitations of the claims.

Claims 1, 3-5, 11, 13-15, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhao et al. (J. Biol. Chem. (Sept. 1995) 270(35): 20763-20774).

Response to Arguments:

Applicants argue that the source of the protein as “bacterial” is not a process limitation but a property of the claimed protein. Because the protein does not exist in isolated form in nature, designation of its source organism defines a property that can distinguish one heme binding protein from another (bacterial from mammalian).

Applicants state that the genetic origin of the Zhao et al. protein is mammalian. This argument has been considered but is not deemed persuasive. The present issue is whether or not the claimed product can be distinguished over the prior art. The claims are drawn to a product. If the prior art teaches a product that is identical to the claimed product, the claimed product is not patentable, even if it comes from another source, unless that source imparts some property that distinguishes the claimed product from the prior art. In the present case, there is not a description in the present Specification or the prior art of what features of the sequence identify heme binding proteins as being "bacterial" or from Archaea or from *H. salinarum*. Thus, without such a description or without any evidence that the proteins of Zhao et al. are distinguishable over the claimed proteins, the claimed proteins do not appear to be patentable over Sugimoto et al.

Rejection:

Zhao et al. disclose the expression, isolation, and purification of recombinant mutant myoglobin in *E. coli* (p. 20764, Col. 2, Materials and Methods). The L29F/H64Z mutant myoglobin is shown to bind oxygen with low affinity as compared to wild-type (see Table I). Therefore, the L29F/H64Z double mutant is considered a heme binding protein that reversibly binds oxygen with low affinity and would have greater than 20% identity to a myoglobin heme binding domain. The limitation in the present claims that the heme binding proteins are bacterial or that they are isolated from Archaea or *H. salinarum* has been treated similarly to a product-by-process (for example, protein made by the process of isolation from bacteria). "[E]ven though product-by-process

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claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production" (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 MPEP 2113 and MPEP 2113)). In the instant case, the Specification does not provide a description of what features of the sequence identify a heme binding protein as being "bacterial" or from Archaea or from *H. salinarum*. Thus, without such a description, the protein and blood substitute described in Grinstaff et al. appears to be patentably indistinguishable from that of the instant claims. The protein is contained in a 0.1 M potassium phosphate buffer and therefore appears to be "salt tolerant". Zhao et al. teach that the disclosed double mutant was constructed for use as a blood substitute (see abstract). Thus, the reference meets the limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Proc. Natl. Acad. Sci (1996) Vol. 93, pp. 4649-4654 ; ref. 16 in IDS of Paper No. 4). In view of Yao and Spudich (Proc. Natl. Acad. Sci. (1992) 89: 11915-11919) and Yao et al. (J. Bacteriol. (1994) 176(22): 6931-6935).

Zhang et al. teach a heme binding protein, HtB, which has 100% identity to the sequence of SEQ ID NO:2 (see sequence alignment attached to this Office Action). Zhang et al. teach that the proteins disclosed therein are from *Halobacterium salinarum*, a member of *Archaea* (p. 4649, Col. 1, last paragraph). The properties of a protein are a function of its sequence. Therefore, it is inherent that the HtB protein disclosed in Zhang et al. has all of the properties of Claims 1-6 (such as reversibly binding oxygen with low affinity, having 20% identity to a myoglobin heme binding domain, salt tolerance, etc.) since these are the properties of the protein of SEQ ID NO: 2. Figure 5 (p. 4653) shows the SDS/PAGE analysis of the proteins from *H. salinarum* after fractionation of soluble and membrane-bound proteins (see Col. 1, lines 15-23). Thus, the protein disclosed in Zhang et al. is considered to be isolated by the fractionation and gel analysis.

Zhang et al. do not specifically teach the purification of HtB or the recombinant expression of HtB.

Yao and Spudich and Yao et al. provide evidence that it was well within the skill in the art, at the time of the present invention, to clone, sequence, recombinantly express and purify a protein based on the information provided in Zhang et al. (protein sequence information, teaching of its isolation and localization in an identified bacterial strain). Yao and Spudich teach the isolation of a protein, Htrl, related to HtB from *H. salinarum* (note that *H. salinarum* is also called *H. halobium*; see Col. 1, lines 3-4 of Introduction). The Htrl gene was cloned and the full length gene sequenced, based on the partial protein sequence (see p. 11917, Results). Yao et al. teach that the related Htrl can be successfully recombinantly expressed in *E. coli* and purified using a Ni²⁺-nitrilotriacetic acid resin (see p. 6932, Col. 1, 2nd and 3rd full paragraphs).

Therefore, it was well within the skill of those in the art and would have been obvious to one of ordinary skill in the art to recombinantly produce and/or purify the HtB protein taught in Zhang et al. Zhang et al. teach how to isolate the HtB protein, where in the cell it is localized, and provide a partial amino acid sequence. It was well within the means of one of ordinary skill in the art at the time of the invention to purify or recombinantly produce proteins like the HtB protein as evidenced by Yao and Spudich and Yao et al. One of ordinary skill in the art would have been motivated to provide HtB of greater purity in order to characterize the function of the protein and to provide a greater understanding of the signaling pathway in which it is involved as suggested in Zhang et al. (p. 4654, last paragraph).

Claim Objections

Claim 6 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions


Claims 1-5, 11-15, 53, and 64-67 are rejected, Claims 6 and 16 are objected to, and Claims 48-50, 52, and 54 appear to be in condition for allowance.


It appears that there is no teaching or suggestion in the prior art of a chimeric protein comprising a bacterial heme binding domain and a heterologous signaling domain or a blood substitute comprising the protein of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Holly Schnizer
December 9, 2003


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800